October 24, 2006

MEMORANDUM

TO: Don Heller, Project Manager

FROM: Daniel Mazur, Ecologist

SUBJECT: Eli Lilly Tippecanoe Laboratories, Lafayette, Indiana
Ecological Risk Assessment
Review Development of 5 Surface Water Ecological Screening Benchmarks and Endpoint Concentration for n,n-Diethylaniline

I have reviewed the calculations by Eli Lilly (Sept. 10, 2004) to develop surface water interim criteria for the following chemicals:

Chemical	CAS #
p-Chlorobenzotrifluoride	98-56-6
n,n-Diethylaniline	91-56-6
Diethyl ether	60-29-7
Hexane	110-54-3
Tetrahydrofuran	109-99-9

The methods used to derive an interim surface water criteria by Lilly and the Region 5 RCRA ecological screening levels are no longer valid. In 1995, a Tier II method[1] to derive a secondary acute value (SAV) was provided by the US EPA (Federal Register, Vol. 60, No. 56, Thursday, March 23, 1995) when all of the eight data requirements for calculating a final acute value (FAV) are not met. This method to calculate both a SAV and a Secondary Continuous Concentration (SCC) is available on pages 15399 and 15400 of the above referenced Federal Register which is available at http://www.epa.gov/gliclearinghouse/docs/usepa_fr_notice_2.pdf
The SCC is the ecological benchmark (not to be exceeded) for continuous contaminant exposure to aquatic life and is equal to the lowest of the Secondary Chronic Value (SCV) or the Final Plant Value, if available. Likewise, if the geometric mean of the acute value or chronic value for a commercially or recreational important species is lower than the calculated SAV or SVC, that value will be used instead.

The following table applies the acute toxicity data provided by Lilly (and verified in the ECOTOX database except for p-Chlorobenzotrifluoride[2]) along with other factors needed to generate a Tier II, SCC (or SCV) for the five chemicals identified above. The interim surface water criteria developed by Lilly are listed in this table for comparison. Except for tetrahydrofuran, all of the SCV are higher than the Lilly final chronic values (FCV). No final plant values were found in the EXOTOC database and important species were noted when data was available. The Tier II values for SCC and SMC (secondary maximum concentration, equal to one-half of the SAV) are presented in the following table. Both the SMC and the SCC are rounded to two significant figures as required by the USEPA 1995 Tier II method.

Criteria to calculate Tier II values (SMC and SCC)

	p-Chlorobenzo trifluoride	n,n-Diethylaniline	Diethyl ether	Hexane	Tetrahydrofuran
Lowest GMAV	12,000 ug/L	1,300 ug/L	165,000 ug/L	2,500 ug/L	1,970,000 ug/L
# of MDR's	3	2	3	5	2
SAF	8.0	13.0	8.0	6.1	13.0
SAV	1,500 ug/L	100 ug/L	20,625 ug/L	409.8 ug/L	151,500 ug/L
SAC Ratio	18	18	18	18	18
SCV	83 ug/L	5.6 ug/L	1,146 ug/L	23 ug/L	8,417 ug/L
Lilly FCV	40 ug/L	0.27 ug/L	1,101 ug/L	0.36 ug/L	25,272 ug/L
Final Plant Value	------	------	------	------	------
Important Species	GMAV is for blue gill	------	GMAV is ‹ blue gill	------	------
SMC	750 ug/L	50 ug/L	10,000 ug/L	200 ug/L	76,000 ug/L
SCC	83 ug/L	5.6 ug/L	1,100 ug/L	23 ug/L	8,400 ug/L

Terms Defined:

GMAV Genus Mean Acute Value (lowest one out of 3 specified genera in Daphnidae family)
MDR Minimum Data Requirements, (taxonomic families as specified in the Tier I method in section III. B. 1 of Appendix A to part 132 - GLWQI)
SAF Secondary Acute Factor (see Table A-1 for the Tier II method)
SAV Secondary Acute Value (= GMAV x SAF)
SAC Ratio Secondary Acute to Chronic Ratio (see section VI of this appendix, default is 18)
SCV Secondary Chronic Value (= SAV) SAC Ratio)
SMC Secondary Maximum Concentration (highest concentration allowed for a brief exposure)
SCC Secondary Continuous Concentration (equal to lowest SCV or final plant value or important species chronic value)

SCV = (GMAV/SAF)/SAC Ratio

The iso-concentration map (figure 6) submitted by Lilly on August 15, 2006 shows the endpoint concentration (monitoring wells adjacent to the Wabash River) for n,n-diethylaniline exceeding the Secondary Continuous Concentration (SCC) . This contaminant also exceeds the highest concentration (SMC) allowed for a brief exposure to aquatic organisms.

[1] Methodology for Deriving Aquatic Life Values: Tier II (Appendix A to part 132–Great Lakes Water Quality Initiative Methodologies for Developments of Aquatic Life Criteria and Values)

[2] Toxicity data for p-Chlorobenzotrifluoride was submitted to the USEPA, Office of Atmospheric Programs under the Significant New Alternatives Policy (SNAP).